

## **REMARKS/ARGUMENTS**

Claims 139-145 are pending in this application. Applicants thank the Examiner for withdrawing the utility and enablement rejections. The rejections to the presently pending claims are respectfully traversed.

### **Claim Rejections - 35 U.S.C. §112, First Paragraph - Written Description**

Claims 139-145 remain rejected under 35 U.S.C. §112, first paragraph, allegedly “as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.” (Pages 2-3 of the instant Office Action).

For the reasons outlined below, Applicants maintain that Claims 139-145, which are directed to a fragment of the nucleic acid sequence of SEQ ID NO: 348 or a complement thereof, of at least 20-100 nucleotides in length are adequately described in the specification as filed.

### **Arguments**

The legal standards for evaluating Written Description was discussed in the previous response. Briefly, whether the Applicants were in possession of the invention as of the effective filing date of an application is a factual determination, reached by the consideration of a number of factors, including the level of knowledge and skill in the art, and the teaching provided by the specification. The inventor is not required to describe every single detail of his/her invention. An Applicant's disclosure obligation varies according to the art to which the invention pertains.

Written description standard is assessed through the eyes of a person of ordinary skill in the art. The present invention pertains to the field of recombinant DNA/protein technology. It is well established that the level of skill in this field is very high since a representative person of skill is generally a Ph.D. scientist with several years of experience. Accordingly, the teaching imparted in the specification must be evaluated through the eyes of a highly skilled artisan as of the date the invention was made. The instant invention, defined by the claims, concerns a fragment of the nucleic acid sequence of SEQ ID NO: 348 or a complement thereof, of at least 20-100 nucleotides in length and further, recite the functional recitation: **"that hybridizes under stringent conditions** to: (a) the nucleic acid sequence of SEQ ID NO: 348 or a complement

thereof," wherein, said stringent conditions use 50% formamide, 5X SSC, 50 mM sodium phosphate (pH 6.8), 0.1% sodium pyrophosphate, 5X Denhardt's solution, sonicated salmon sperm DNA (50 µg/ml), 0.1% SDS, and 10% dextran sulfate at 42°C, and washes at 42°C in 0.2X SSC, at 55°C in 50% formamide followed by a high-stringency wash at 55°C in 0.1X SSC, EDTA; wherein said isolated nucleic acid molecule is suitable for PCR use as a PCR primer or probe. (Emphasis added).

Applicants submit that recitation of the detailed, high-stringency, hybridization conditions used to identify the DNA fragments adequately meets the Written description standard, for example, see Example 9 of the Synopsis of Application of Written Description Guidelines issued by the U.S. Patent Office.

Example 9 of the Synopsis of Application of Written Description Guidelines clearly states, regarding genus analysis of nucleic acids where a single species (*i.e.*, a molecule consisting of a fragment of the nucleic acid sequence of SEQ ID NO: 348) is disclosed, and further, where actual reduction to practice has occurred of the disclosed species that, a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because, the highly stringent hybridization conditions set forth in the claim, yield structurally similar DNAs. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions, in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that the Applicant was in possession of the claimed invention. Based on the well-known knowledge in the nucleic acid arts, one skilled in the art would know that the Applicants were in possession of the DNA fragments, especially in view of the detailed disclosure in the specification for: cloning, preparation of DNA fragments, preparation of PCR primers and the actual reduction to practice of sequence SEQ ID NO: 348. Therefore, the claims fully meet the requirements of 35 U.S.C. §112, first paragraph, as providing adequate written description. Hence, Applicants respectfully request that this rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

**Claim Rejections-35 U.S.C. §112, Second Paragraph**

Claims 139-145 remain rejected under 35 U.S.C. §112, second paragraph, allegedly as being "indefinite because of the phrase 'is suitable for use as a PCR primer or probe.'" (Page 5 of the instant Office Action).

Applicants have amended Claim 139 according to the Examiner's suggestion; *i.e.*, to recite "is suitable for PCR use as a PCR primer or probe." Accordingly, Applicants submit that the claims are definite and respectfully request that this rejection be withdrawn.

**CONCLUSION**

The present application is believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

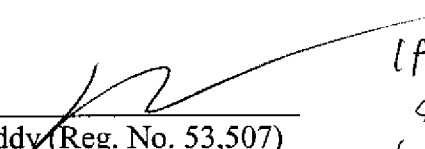
Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. **08-1641** (referencing Attorney's Docket No. **39780-2730 P1C62**).

Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

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